K121412

JUN - 8 2012

Special 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 872.1800.

Date

5/2/2012

Manufacturer

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Contact person: Mr. Dave Kim (davekim@mtech-inc.net)

Trade/Proprietary Name:

PaX-Flex3D (PHT-7000)

Common Name:

Dental Computed Tomography X-ray System

Classification Name:

X-ray, Tomography, Computed, Dental (21CFR 892.1750, Product code **OAS**, Class2)

Description:

PaX-Flex3D (PHT-7000), a dental radiographic imaging system, consists of dual image acquisition modes; panoramic, cephalometirc and cone beam computed tomography. Specifically designed for dental radiography of the teeth or jaws, PaX-Flex3D (PHT-7000) is a complete dental X-ray system equipped with x-ray tube, generator and dedicated SSXI detector for dental panoramic, cephalometric and cone beam computed tomographic radiography. The dental CBCT system is based on CMOS digital X-ray detector. CMOS CT detector is used to capture radiographic diagnostic images of oral anatomy in 3D for dental treatment such as oral surgery or implant. The device can also be operated as the panoramic and cephalometric dental x-ray system based on CMOS X-ray detector.

Indication for use:

PaX-Flex3D is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and x-ray technicians.

Predicate Device:

Manufacturer	: Vatech Co., Ltd
Device	: PaX-Flex-3D
510(k) Number	: K102259 (Decision Date – 2/18/2011)

Substantial Equivalence:

PaX-Flex3D (PHT-7000) described in this 510(k) has the similar intended use and technical characteristics as PaX-Flex3D of Vatech Co., Ltd.

Characteristic	**Proposed** **Vatech Co., Ltd.** ***PaX-Flex3D (PHT-7000)***	**Predicate** **Vatech Co., Ltd.** ***PaX-Flex3D***

510(k) number	K121412	K102259
Indications for use	PaX-Flex3D is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry . The device is operated and used by physicians, dentists, and x-ray technicians.	PaX-Flex3D is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry . The device is operated and used by physicians, dentists, and x-ray technicians.
Performance Specification	Panoramic, cephalometric and computed tomography	Panoramic, cephalometric and computed tomography
Input Voltage	AC 100-120/200-240 V	AC 110/230 V
Tube Voltage	50-90 kV	50-90 kV
Tube Current	2 ~10 mA	4 ~10 mA
Focal Spot Size	0.5 mm	0.5 mm
Exposure Time	1.9 – 24 s	9 – 24 s
Slice Width	0.1 mm min.	0.1 mm min.
Total Filtration	2.8 mmAl	2.8 mmAl
Performance Specification	Computed tomography	Computed tomography
Mechanical	Compact design	Compact design
Electrical	LDCP logic circuit	LDCP logic circuit
Software	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Anatomical Sites	Maxillofacial	Maxillofacial

Image Receptor	***Computed Tomography*** *(Flat Panel Detector)*	*Xmaru0712CF*	-
		Xmaru1215CF Plus	-
		-	*Xmaru0808CF*

		Panoramic *(CMOS photodiode array)*	*Xmaru1501CF*	*Xmaru1501CF*
		Cephalo Metric *(CMOS photodiode array)*	*Xmaru2301CF*	*Xmaru2301CF*
Size of Imaging Volume		***Xmaru0712CF***	5 x 5 *cm* / 8 x 5 *cm* / 8 x 8 *cm*	-
		Xmaru1215CF Plus	5 x 5 *cm* / 8 x 5 *cm* / 8.5 x 8.5 *cm* /12 x 8.5 *cm*	-
		Xmaru0808CF	-	5 x 5 *cm* / 8 x 5 *cm*
Pixel Resolution	***CT***	***Xmaru0712CF***	3.5 *lp/mm*	-
		Xmaru1215CF Plus	3.5 *lp/mm*	-
		Xmaru0808CF	-	3 *lp/mm*
	Pano	***Xmaru1501CF***	5 *lp/mm*	5 *lp/mm*
	Ceph	***Xmaru2301CF***	5 *lp/mm*	5 *lp/mm*
Pixel Size	***CT***	***Xmaru 0712CF***	140 x 140 ㎛	-
		Xmaru 1215CF Plus	140 x 140 ㎛	-
		Xmaru 0808CF	-	150 x 150 ㎛
	Pano	***Xmaru 1501CF***	100 x 100 ㎛	100 x 100 ㎛
	Ceph	***Xmaru 2301CF***	100 x 100 ㎛	100 x 100 ㎛

Indications for use, safety characteristics, and non-clinical performance for panoramic, cephalometric and CBCT sensors of PaX-Flex3D (PHT-7000) and PaX-Flex3D are similar. The primary differences are as follows: PaX-Flex3D (PHT-7000) introduces two new cone beam CT sensors:

Xmaru0712CF and Xmaru1215CF Plus. The non-clinical performance and clinical consideration report for the new SSXI CBCT sensors are provided separately in this submission. Based on the non-clinical and clinical consideration and the outcome of an expert review of image comparisons for both devices, new PaX-Flex3D (PHT-7000) is substantially equivalent, in terms of safety and effectiveness, with PaX-Flex3D, the predicate device.

Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1(A1+A2, 1995), IEC 60601-1-1 (2001), IEC 60601-1-3 (Ed. 1, 1994), IEC 60601-2-7 (1998), IEC 60601-2-28 (Ed. 1, 1993), IEC 60601-2-32 (Ed. 1, 1994) and IEC 60601-2-44 (Ed. 2, 2002) were performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2.

PaX-Flex3D (PHT-7000) meets the provisions of NEMA PS 3.1-3.18, Digital Imaging and Communications in Medicine (DICOM) Set.

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" were performed.

Acceptance test according to IEC 61223-3-4 and IEC 61223-3-5 was performed.

All test results were satisfactory.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification. Vatech Co., Ltd. concludes that PaX-Flex3D (PHT-7000) is safe and effective and substantially equivalent to predicate device as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Vatech Co., Ltd.
% Mr. Dave Kim
Official correspondent (U.S. designated agent)
Mtech group
12946 Kimberly Lane
HOUSTON TX 77079

JUN - 8 2012

Re: K121412
Trade/Device Name: PaX-Flex3D (PHT-7000)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: May 11, 2012
Received: May 11, 2012

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known):

Device Name: PaX-Flex3D (PHT-7000)

Classification: Computed tomography X-ray system

Indications for Use:

PaX-Flex3D is a computed tomography x-ray system intended to produce panoramic, cephalometric or cross-sectional images of the oral anatomy on a real time basis by computer reconstruction of x-ray image data from the same axial plane taken at different angles. It provides diagnostic details of the anatomic structures by acquiring 360° rotational image sequences of oral and maxillofacial area for a precise treatment planning in adult and pediatric dentistry. The device is operated and used by physicians, dentists, and x-ray technicians.

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121412

Concurrence of CDRH, Office of Device Evaluation(ODE)